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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,224	12/09/2003	Neil P. Desai	225602	4904

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,224	DESAI ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) *19-76, 85-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 77-84, 91-93* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/12/04, 12/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Invention I, claims 1-18, 77-84, 91-93, filed December 23, 2004 is acknowledged. The traversal is on the ground(s) that the search will overlap between Groups I and Groups II-VII, and will, therefore, not impose a serious burden on the Examiner. This is not found persuasive because Groups I-VII are independent and distinct inventions as explained in the test of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-36, 37-43, 44-50, 51-63, 64-76, 85-90 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 1-18, 77-84, 91-93 are currently under examination.

Priority: The instant application was filed December 9, 2003. This application claims priority to provisional applications 60/432,317, filed December 9, 2002; 60/526,544, filed December 3, 2003; 60/526,773, filed December 4, 2003; and 60/527,177, filed December 5, 2003. Therefore, the priority date is December 9, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 3 is drawn to a pharmaceutical agent selected from the group as disclosed in the claim, and its derivatives. As written, the claim is drawn to a numerous number of derivatives of any of the pharmaceutical agents listed in the claim. There is no clear or definite guidance as to the degree of change that is necessary to constitute a derivative of the pharmaceutical agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 77-84, 91-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 18, 77, 80, 91 are drawn to a pharmaceutical composition that comprises an effective amount of a pharmaceutically acceptable carrier to reduce one or more side effects. The claims are indefinite because neither the claims nor the specification disclose an explicit numerical value as to what constitutes an effective amount. In addition, there is no clear definition of what the side effect is.

Regarding claims 5-6, 10-11, 17, 77-82, 84, 91-93, the phrase "about" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed

(those encompassed by "about"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 2-4, 9, 14 are included in this rejection because they are dependent on Claim 1.

Claims 7, 15 are included in this rejection because it is dependent on Claim 5.

Claim 8 is included in this rejection because it is dependent on Claim 6.

Claims 12, 13, 16 are included in this rejection because it is dependent on Claim 10.

Claim 83 is included in this rejection because it is dependent on Claim 80.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (Yang et al. 1993 Biochem. Pharm. 46(2) : 336-339). Yang et al. teach human serum was mixed with 4 vol. of Tris buffer and incubated with 5.5 μCi/mL of [^{3}H] dihydroartemisinin for 24 hr at 37° in the presence of deferoxamine (DFO, 1 mM) (p. 336; claims 1, 2, 5, 18). Yang et al. teach a mixture of human serum and Tris-HCl buffer (250 mM, pH 8.0) in a 1:4 v/v (p. 336). The composition of Yang et al., therefore meets the limitation of 25% by weight of albumin in claim 5. Yang et al. do not specifically teach the role or function of deferoxamine in the composition. However, the properties of inhibiting microbial growth (claim 1) and inhibiting oxidation (claim 18) are

properties that are inherent to deferoxamine. It is known in the art that artemisinin is an effective anti-cancer agent (Singh et al. 2001 Life Sciences 70: 49-56).

Claims 1, 5-6, 9-11, 18 are rejected under U.S.C. 102(b) as being anticipated by Ritov et al. (Ritov et al. 2001 Diabetes 50 : 1253-1262). Ritov et al. teach a medium comprising 100 mmol/l mannitol, 5.0 mg/ml bovine serum albumin (BSA), 100 umol/l deferoxamine mesylate, 20 umol/l leupeptin, etc. (p. 1254, preparation of homogenate; claims 1, 5-6, 9-11, 18). Ritov et al. teach a 5.0 mg/ml or 0.005 g/ml concentration of BSA (p. 1254). The weight/volume percent can often be used to calculate the percentage concentration. The volume of a solution in mL is very nearly numerically equal to the mass of the solution in grams (art of reference: Eggling). Therefore, the formuation of Ritov et al. comprises 0.5% of albumin by weight in a 1 ml volume of a composition (claims 5-6). The molar mass of deferoxamine mesylate is 656.79 g/mol (art of reference: drugs.com). Ritov et al. teach a 6.6×10^{-5} g/ml concentration of deferoxamine mesylate, that comprises 0.0066% by weight of deferoxamine myesylate in a 1 ml volume of the composition (claims 9-11). Though Ritov et al. do not specifically address the functions of inhibiting microbial growth (claim 1) and inhibiting oxidation (claim 18) in the composition, the limitations of claim 1 and claim 18 are met because these are properties that are inherent to deferoxamine. It is known in the art that leupeptin can inhibit muscle degeneration.

Claims 77-83, 91-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Paal et al. (Paal et al. 2001 Eur. J. Biochem. 268: 2187-2191). In order to minimize vehicle-related toxicity, Paal et al. teach a novel, water-soluble formulation in which

paclitaxel is bound covalently to human serum albumin. Paclitaxel is a very potent antitumor agent. Paal et al. teach a sample preparation comprising of 3 μM albumin, 1% ethanol, and 0.5-150 μM paclitaxel (pH 6.5, 2.4 μM Cl^-) (p. 2188, sample preparation; claims 77-83, 91-93). The claims are drawn to a ratio of albumin to pharmaceutical agent at of 18:1 or less. The ratio of 3 μM albumin to 0.5 μM paclitaxel is 6:1. Even though this ratio is less than the ratios of 18:1, 12:1, and 9:1 of claims 80-82, respectively, it still meets the claim limitations.

Double Patenting

Claims 77-79, 91-93 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 10 of copending Application No. 10616709. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 10616709 anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Cochrane Carlson PhD

February 4, 2005

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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